REMARKS

In the Office Action dated January 29, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121 and §372, alleging that the subject matter defined by the claims of the present invention represents the following four separate and distinct inventions:

Group I	Claims 1-9 and 20, drawn to an animal or avian species modified to have reduced levels of Bcl-w protein.
Group II	Claims 1, 4, and 5, drawn to an animal or avian species modified to have reduced levels of a Bcl-w-associated protein.
Group III	Claims 12-19, drawn to an animal or avian species modified genetically to have a mutation in Bcl-w.
Group IV	Claims 14 and 15, drawn to an animal or avian species modified genetically to have a mutation in a gene associated with Bcl-w.

The Examiner has not included Claims 10 and 11 in any of the groups, alleging that these claims are unclear. The Examiner further alleges that the above-identified groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, allegedly because these groups lack the same or corresponding special features under PCT Rule 13.2. Specifically, the Examiner contends that the above-identified groups do not fall within the allowed combinations of groups of inventions under MPEP§1850 that would satisfy the unity requirement. In the Examiner's opinion, Groups I and II encompass an animal modified through non-transgenic mechanisms to alter Bcl-w protein levels. Animals encompassed by these groups can include those administered drugs or those altered by some other means that does not alter the genetic makeup of the animal such as gene therapy. The Examiner also contends that Group II encompasses indirect reduction of Bcl-w protein levels by affecting proteins associated with Bcl-

w. Additionally, the Examiner contends that Groups III and IV encompass transgenic animals with an altered genome. Group III includes animals with an altered Bcl-w gene and Group IV encompasses animals with alteration in a gene other than Bcl-w that encodes a product associated with Bcl-w. Therefore, the Examiner concludes that Groups I-IV represent different products with distinct material compositions and uses.

Furthermore, the Examiner states that claims 2, 3, 12 and 20 read on patentably distinct Groups drawn to multiple SEQ ID Numbers. The Examiner contends that SEQ ID Nos. 1-5 and 7 are patentably distinct, because each of the sequences are unrelated, as such a further restriction is applied to the sequences. Therefore, the Examiner requires Applicants to elect a single nucleotide and the corresponding polypeptide sequence.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims 1-9 and 20, drawn to an animal or avian species modified to have reduced levels of Bcl-w protein. Applicants further provisionally elect, with traverse, SEQ ID NO: 1 directed to human Bcl-w nucleotide sequence, and SEQ ID NO: 2, directed to human BCL-W polypeptide sequence, in response to the Sequence Election Requirement.

In addition, Applicants have amended claim 10 to replace the term "exposure" with the term "expression". Claims 10-11, as presently amended, are drawn to an animal or avian species modified to contain an introduced genetic molecule capable of inhibiting or reducing expression of the bcl-w gene. Applicants therefore respectfully request that claims 10-11 be included in Group I for examination.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

Applicants submit that Groups I-IV are not distinct as the Examiner has alleged, but rather represent one single inventive concept warranting examination in a single application. More specifically, the present inventors uniquely recognized that an animal or an avian species deficient for bcl-w or a gene associated with bcl-w fails to undergo productive spermatogenesis and is fertile without showing any other major abnormality. Therefore, the present invention provides animals or avian species modified to have reduced levels of BCL-W protein (Group I) or have reduced levels of a protein associated with BCL-W (Group II). The present invention also provides animals or avian species modified to have a mutation in the bcl-w gene (Group III) or in a gene associated with the bcl-w gene (Group IV), where such animal or avian species can be substantially infertile (see, e.g., claim 18). Applicants respectfully submit that Groups I-IV are embodiments linked to each other under the single inventive concept that an animal or an

avian species deficient for bcl-w or a gene associated with bcl-w fails to undergo productive spermatogenesis. Applicants respectfully submit that Groups I-IV are merely different aspects of a single invention.

As to the sequences, SEQ ID NO: 1 and SEQ ID NO: 3 set forth human and murine bcl-w nucleotide sequences, respectively. The two sequences share a significant degree of identity. The corresponding protein sequences, as set forth in SEQ ID NO: 2 and SEQ ID NO: 4, also share a significant degree of identity and apparently perform similar functions. SEQ ID NO: 5 and SEQ ID NO: 7 set forth nucleotide sequences of derivatives of human bcl-w and murine bcl-w, respectively. Clearly, all these sequences are related to each other, both structurally and functionally, as different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Accordingly, it is respectfully submitted that claims 1-20 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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